UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/571,184	07/17/2006	David Morton	478.1077	9629

23280 7590 11/05/2008

Davidson, Davidson & Kappel, LLC
485 7th Avenue
14th Floor
New York, NY 10018

EXAMINER	
OLSON, ERIC	
ART UNIT	PAPER NUMBER
1623	
MAIL DATE	DELIVERY MODE
11/05/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,184	MORTON ET AL.	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *April 17, 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

This application is a national stage application of PCT/GB04/03932, filed September 14, 2004, which claims priority to foreign applications GB0321611.6, filed September 15, 2003, and GB0327723.3, filed November 28, 2003. Claims 1-3 and 5-46 are pending in this application and examined on the merits herein. Applicant's preliminary amendment submitted is acknowledged wherein claims 1, 3, 5-7, 9-25, 27-31, 33-35, and 37-40 are amended, claim 4 is cancelled, and new claims 41-46 are introduced.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 9-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compositions and methods utilizing specific mucoactive agents such as glycosaminoglycans, does not reasonably provide enablement for methods and compositions comprising any possible mucoactive agent whatsoever. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a

disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is a composition comprising a mucoactive agent and methods of making and using said composition. In order to be able to make and use the invention one skilled in the art must be able to obtain any and all of the mucoactive agents included in the scope of the invention, by synthesis or isolation from a natural source.

The state of the prior art: Various mucoactive agents are known in the prior art which can induce a response when inhaled. However, the prior art does not exhaustively list all of the possible compounds which could conceivably produce this sort of activity, or provide any means by which one skilled in the art could determine in advance the entire scope of compounds that would possess this activity.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: The biological activities of chemical compounds are unpredictable. While there is a presumption that similar structures indicate similar effects, it is also possible for compounds with different structure to produce the same or similar biological effects. Therefore there is no way to determine the full scope of compounds having a given activity merely by contemplating

other known compounds having the same activity. Instead one skilled in the art must screen a wide selection of candidate compounds in order to determine which ones have the desired activity.

The Breadth of the claims: The claimed invention is very broad, encompassing compounds of any structure whatsoever provided that it possesses mucolytic activity.

The amount of direction or guidance presented: While certain mucoactive agents, such as glycosaminoglycans, DNAse, or dextrans are disclosed in the specification as being useful in the claimed invention, these compounds are not seen to be representative of all possible mucoactive agents that would be included within the breadth of the claims.

The presence or absence of working examples: Applicant's disclosure does not provide any working examples of actual therapeutic benefit in a living subject.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the discovery of novel active agents. See MPEP 2164.

The quantity of experimentation necessary: One of ordinary skill in the art, in order to practice the claimed invention with the full range of mucolytic agents beyond the meager number disclosed in the specification would be required to test potential compounds *in vivo* to determine whether a particular compound is useful as a mucolytic agent. According to the 2006 Chemical Abstracts catalog, (Reference included with PTO-892) The Chemical Abstracts Registry contains entries for approximately 26 million compounds, all of which are potentially included in the claimed invention if they happen

to have mucolytic activity. For most compounds, it is unknown whether they are or are not useful as mucolytic agents. Gathering this data for every compound known to man would involve *in vitro* screening of an enormous diversity of chemical compounds for mucolytic activity, as well as *in vivo* testing of compounds having this activity involving either human or animal subjects to determine therapeutic utility. *In vitro* testing requires that the compounds to be tested be synthesized and subjected to an appropriate screening method. As described earlier, synthesis of diverse chemical structures requires novel and unpredictable experimentation in order to develop suitable synthetic methods. *In vivo* animal experiments include, along with induction of the disease state, administration of the potential pharmaceutical compound and collection and analysis of data, additional burdens associated with compliance with animal welfare regulations, care, feeding, and other maintenance of the animals, dissection of dead animals to collect data, and disposal of dead animals after the protocol is finished. Human tests impose even greater ethical and regulatory burdens, as well as additional difficulty locating subjects. Because of the unpredictability of the art and the lack of comprehensive working examples covering any significant portion of the total number of potential mucolytic agents, these animal experiments would need to be repeated hundreds of times, and involve the maintenance, killing, dissection, and disposal of thousands of experimental animals, to establish the activity or lack thereof of every possible mucolytic agent, thus presenting an a burden of undue experimentation to anyone practicing the invention with the full range of mucolytic agents claimed.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims and the lack of guidance or working examples, Applicants fail to provide information sufficient to practice the claimed invention for all possible mucolytic agents.

Claims 26 and 29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods and compositions for treating specific pulmonary diseases such as asthma or chronic obstructive pulmonary disease, does not reasonably provide enablement for compositions and methods for treating any and all pulmonary diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims;

(6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: The claimed invention is a composition and method for the treatment of a broad class of diseases. In order to be enabled broadly for treating these diseases, one skilled in the art must have an enabling disclosure or a representative sample of the full range of claimed diseases.

The state of the prior art: Heparin is known in the prior art to be useful in inhaled formulations for treating certain pulmonary diseases such as asthma, allergy, or cystic fibrosis. However, inhaled heparin has not been shown to be broadly useful for all possible pulmonary diseases.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: Pulmonary disease includes a wide range of disorders, for example genetic diseases such as cystic fibrosis, diseases caused by exposure to environmental factors such as allergens, cigarette smoke, or asbestos, and infections by pathogenic organisms such as tuberculosis, pneumonia, or anthrax. With no one single cause or mechanism unifying all pulmonary disease, it would not be expected that one single therapeutic approach or compound would treat all pulmonary diseases.

Determining the therapeutic utility of a particular compound against unrelated diseases is an unpredictable process as utility against one specific disease does not thereby guarantee utility against other unrelated diseases.

The Breadth of the claims: The claimed invention is very broad, encompassing all pulmonary diseases regardless of origin, mechanism, or symptoms.

The amount of direction or guidance presented: The specification is primarily concerned with refinements in the methods for making fine powders for inhalation. Although heparin is disclosed to have mucolytic activity, it is not shown in Applicant's disclosure to have broader activity against all types of pulmonary disease.

The presence or absence of working examples: No working examples are provided for the treatment of diseases in living subjects.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as the broad-spectrum treatment of unrelated diseases. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the claimed invention for the treatment of all pulmonary diseases generally, one skilled in the art would have to undertake experimentation in a wide variety of disease models in order to validate the claimed therapeutic agents against a sufficiently representative sample of pulmonary diseases. Doing so would require an unpredictable process of original research for each disease indication evaluated, leading to an undue and unpredictable experimental burden for one skilled in the art in order to practice the invention.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims and the unpredictability of the art, Applicants fail to provide information sufficient to practice the claimed invention for all possible pulmonary diseases.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-10, 15, and 25-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahmed et al. (PCT international publication WO99/06025, reference included with PTO-1449)

Ahmed et al. discloses a method of treating conditions characterized by late phase allergic reactions (e.g. asthma) by administering an ultra-low molecular weight heparin, or ULMWH. (p. 6 line 14 – p. 7 line 15) the ULMWH has little or no anticoagulant activity and is administered as a pharmaceutical composition which is an inhalable powder. (p. 7 lines 16-21) Besides ULMWH, the inhalable compositions can also comprise other sulfated polysaccharides such as dermatan sulfate, chondroitin sulfate, pentosan polysulfate and/or other glycosaminoglycans and mucopolysaccharides. (p. 20 lines 1-10) Suitable powder compositions include compositions of heparin intermixed with inert powders such as lactose and delivered through an inhaler device. (p. 21 lines 14-19) Other claimed properties of the powder,

namely its utility in certain therapeutic indications as recited in claims 25-28, are inherently present in these pharmaceutical compositions, as they are identical to those disclosed in the instant specification to be useful for treating these diseases. Therefore Ahmed et al. anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12, 14, 16-24, 30 and 40-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmed et al. (PCT international publication WO99/06025, reference included with PTO-1449) as applied to claims 1-3, 5-10, 15, and 25-29 above, and further in view of Staniforth. (PCT international publication WO97/03649)

The disclosure of Ahmed et al. is discussed above. Ahmed et al. does not disclose compositions comprising the specific particle sizes or additives included in the aforementioned claims, or a method comprising spray drying said composition.

Staniforth discloses a powder for use in a dry powder inhaler comprising an active material and an anti-adherent material, where the active material makes up at least 60% of the weight of the powder. (p. 4 lines 6-11) The active material used in these compositions can be a carbohydrate, for example heparin. (p. 11 lines 21-22) Anti-adherent materials can include additives such as leucine, an amino acid, or lecithin,

a phospholipid, which are force control agents according to the limits of the instant claims, and additional additives such as lactose. (p. 5 line 32 – p. 6 line 9) N-acetyl-L-cysteine is another additive that can be used. (p. 9 lines 34-37) In a preferred embodiment at least 90% of the composition is made up of particles of active agent (fine particles) which have a diameter of about 0.1-5 μm. (p. 8 lines 26-36) Example 1 discloses a dry powder mixture wherein the active agent particles have a MMAD of 2.1 μm with about 1% leucine by weight. (p. 18 lines 1-21) The optimal size for the agglomerates of active agent and carrier particles is at least 45 μm, indicating that it is preferable to use carrier particles of at least 45 μm. (p. 5 lines 11-27)

It would have been obvious to one of ordinary skill in the art at the time of the invention to make a powder composition of ULMWH of the type described by Ahmed et al. incorporating anti-adherent particles as described by Staniforth. One of ordinary skill in the art at the time of the invention would have been motivated to incorporate the anti-adherent particles described by Staniforth because Staniforth discloses that the anti-adherent particles improve delivery of active agents by inhalation. One of ordinary skill in the art would have reasonably expected success because Staniforth discloses that these methods can be used to formulate inhalable powders for the delivery of heparin.

Furthermore, with respect to the specific particle size of claim 23 or composition of claim 43, one of ordinary skill in the art would have recognized that the disclosure of Staniforth covers a broad range of particle sizes and compositions, and would have been able to adjust the specific amounts with in the disclosed ranges to arrive at the

optimal value within the prior art disclosure. Doing so is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmed et al. (PCT international publication WO99/06025, reference included with PTO-1449) in view of Staniforth (PCT international publication WO97/03649) as applied to claims 12, 14, 16-24, 30, and 40-46 above, and further in view of Dunbar et al. (Reference included with PTO-892)

The disclosure of Ahmed et al. in view of Staniforth is discussed above. Ahmed et al. in view of Staniforth does not disclose a method wherein the particles of heparin are spray dried at a controlled velocity of less than 20 m/s or one where the droplets are generated by an ultrasonic nebuliser.

Dunbar et al. discloses a method of spray drying that can be used to form dry powder aerosol formulations for inhalation, using either an ultrasonic nebuliser or an airblast nebuliser. (p. 434, left column paragraphs 1-2) The droplet velocities produced by the ultrasonic nebuliser ranged from 0.47-1.09 m/s. (p. 436, right column last paragraph)

It would have been obvious to one of ordinary skill in the art at the time of the invention to make the powders as taught by Ahmed et al. in view of Staniforth by spray drying using an ultrasonic nebuliser. One of ordinary skill in the art would have been motivated to make the particles by this method because Dunbar et al. discloses that

spray drying using an ultrasonic nebuliser is a suitable method for making inhalable dry powders having the required properties. One of ordinary skill in the art would reasonably have expected success because spray drying is a common and well-characterized method of making pharmaceutical powder formulations.

Therefore the invention taken as a whole is *prima facie* obvious.

Claims 11 and 35-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmed et al. (PCT international publication WO99/06025, reference included with PTO-1449) in view of Staniforth (PCT international publication WO97/03649) as applied to claims 12, 14, 16-24, 30, and 40-46 above, and further in view of Chickering et al. (US pre-grant publication 2004/0121003, cited in PTO-892)

The disclosure of Ahmed et al. in view of Staniforth is discussed above. Ahmed et al. in view of Staniforth does not disclose a method wherein the particles of heparin are jet milled at an inlet pressure of 0.1-3 bar or 2-12 bar, or wherein at least 90% by volume of the active particles are less than 20 μm in diameter prior to jet milling.

Chickering et al. discloses a method for making a dry powder blend comprising jet milling particles of a pharmaceutical active agent with larger particles of an excipient. (p. 1 paragraph 0009) Excipient particles are preferably 40-100 μm in diameter and can include sugars and amino acids, such as lactose, mannitol, leucine, or cysteine. (pp. 1-2, paragraph 0010) The microparticles to be jet milled can be formed by spray drying. (p. 2 paragraph 0013) The process substantially maintains the size and morphology of

the individual microparticles while deagglomerating them. The jet mill can be operated at any pressure between 0 and 10 bar. (p. 10 paragraph 0130)

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the jet milling procedure of Chickering et al. to prepare a particle blend as described by Ahmed et al. in view of Staniforth. One of ordinary skill in the art would have been motivated to use this method because Chickering et al. already discloses that the method is useful for making a blend of fine active particles with carrier particles. One of ordinary skill in the art would have reasonably expected success because jet milling is already known in the art as a routine method of making pharmaceutical powders.

With regard to the initial particle size listed in instant claim 39, one of ordinary skill in the art would have recognized that since the jet milling process substantially preserves the size of individual particles, the active particles used in this process should already be of the desired size, which is much less than 20 µm.

Therefore the invention taken as a whole is *prima facie* obvious.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmed et al. (PCT international publication WO99/06025, reference included with PTO-1449) as applied to claims 1-3, 5-10, 15, and 25-29 above, and further in view of Stossel et al. (US patent 5464817, cited in PTO-892)

The disclosure of Ahmed et al. is discussed above. Ahmed et al. does not disclose a composition comprising rhDNAse.

Stossel et al. discloses a method of disaggregating actin, reducing the polymerization of free actin, and inhibiting the binding of actin to DNAse I, said method comprising administering an actin binding compound to the respiratory tract of a subject. (column 5 lines 45-65) This method can include addition of exogenous DNAse (column 6 lines 47-51) or preferably gelsolin or thymosin β4. (column 12 lines 29-34) Diseases treatable in this manner include various pulmonary diseases such as cystic fibrosis, chronic bronchitis, mucopurulent or purulent exacerbation of simple mucoid bronchitis, bronchorrhea, bronchopneumonia, widespread bronchiolitis, purulent pneumonia, pneumonic-alveolar-consolidation, asthma, with or without asthmatic bronchitis with mucus plugging, acute and/or chronic purulent sinusitis, empyema, bronchiectasis, bronchocoele, adult respiratory distress syndrome (ARDS), post-transplantation obliterative bronchiolitis, and allergenic bronchiolitis (fibrosing alveolitus), for example. (column 7 lines 11-21) These drugs can be administered by inhalation. (column 10 lines 62-67)

It would have been obvious to one of ordinary skill in the art at the time of the invention to add gelsolin or thymosin β4 to the therapeutic compositions of Ahmed et al. One of ordinary skill in the art would have been motivated to make the combination because Stossel et al. discloses these compounds to be useful for treating the same indications as the compounds of Ahmed et al., namely pulmonary diseases such as asthma. One of ordinary skill in the art would reasonably have expected success because combining two known prior art compositions known to be useful for the same purpose is well within the ordinary and routine level of skill in the art.

Therefore the invention taken as a whole is *prima facie* obvious.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ahmed et al. (PCT international publication WO99/06025, reference included with PTO-1449) as applied to claims 1-3, 5-10, 15, and 25-29 above, and further in view of Trofast. (US patent 6027714, cited in PTO-892)

The disclosure of Ahmed et al. is discussed above. Ahmed et al. does not disclose a composition comprising mannitol or glucose.

Trofast discloses a composition for inhalation comprising budesonide and a carrier substance. (column 1 lines 23-28) The carrier substance is preferably a saccharide such as glucose or a sugar alcohol such as mannitol. (column 1 lines 34-39)

It would have been obvious to one of ordinary skill in the art to use glucose or mannitol as an inert powder carrier in the compositions of Ahmed et al. One of ordinary skill in the art would have been motivated to use these specific carriers because Trofast already discloses that they are useful as inert carriers for inhalable dry powders. One of ordinary skill in the art would reasonably have reasonably expected success because Ahmed et al. already disclose that any conventional inert carrier substance can be used in the disclosed compositions.

Therefore the invention taken as a whole is *prima facie* obvious.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/
Examiner, Art Unit 1623
11/03/2008

/Shaojia Anna Jiang/
Supervisory Patent Examiner, Art Unit 1623